


Exhibit 248 [replacing Dkt. #1964-35] attached to Plaintiffs' Memorandum of Law in Support of Motion for Partial Summary Adjudication that Defendants did not Comply with Their Duties under the Federal Controlled Substances Act to Report Suspicious Opioid Orders and Not Ship Them (Second Corrected) at Dkt. #1910-1.

- Redactions withdrawn by Defendant

EXHIBIT 248

	<p style="text-align: center;">Lifestyle Drug Program</p> <p style="text-align: center;">McKesson U.S. Pharma – DEA Licensure Audit</p>
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Last Revised Date:	July 27, 2007

Overview

The Lifestyle Drug Program is a response to the DEA's requirement to monitor the ordering/sales of DEA identified "Lifestyle Drugs" and to "know your customer". A legitimate patient/doctor relationship is required to dispense all drugs containing any of the substances on the DEA Lifestyle Drug list. The need for a Lifestyle Drug Monitoring Program originated from issues with illegitimate internet pharmacies. The DEA has not specified how sales of the substances should be monitored and the directive is somewhat vague.

The Lifestyle Drug Program was rolled out to the DCs in May 2007 and fully implemented in all of the DCs as of June 1st 2007. This is currently a very manually process. However, efforts to automate are underway.

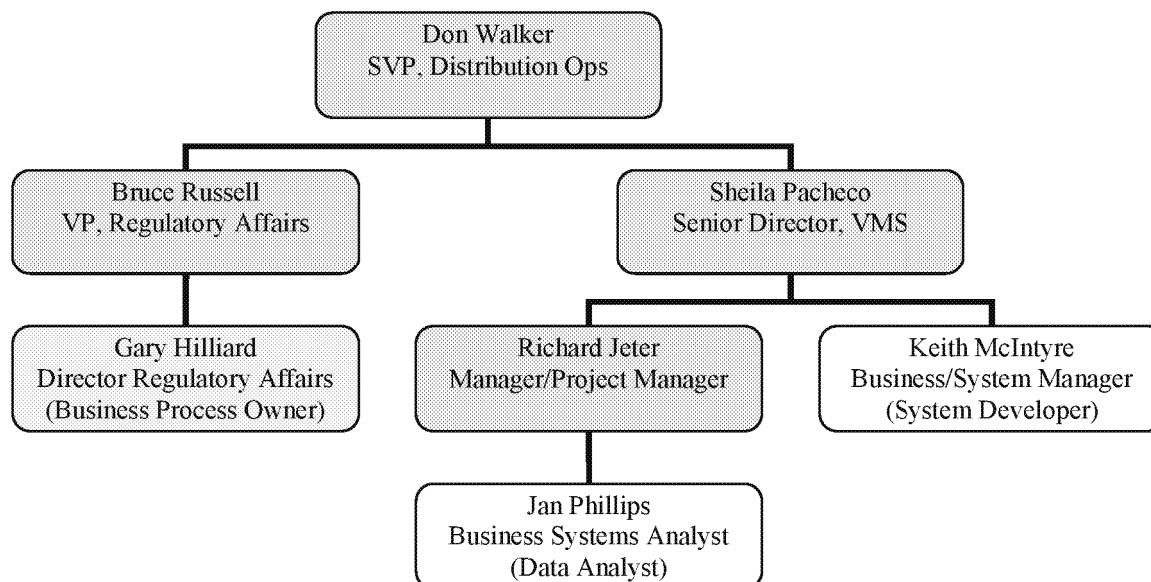
Background

The following narrative documents the **McKesson Lifestyle Drug Monitoring Program**. The table below summarizes this process (details of the process will follow). The table also indicates the specific financial statement line items that are impacted by the process:

Process Start and End Description	<ol style="list-style-type: none"> 1. Order received and sale recorded. 2. Report run to identify sales of Lifestyle Drugs that exceed a monthly threshold. 3. Report is reviewed by DCM. The review follows a 3-tier process and is documented at each level. 4. Based on results of DCM review, appropriate action to adjust order quantities are taken when deemed necessary.
Financial Statement Account(s)	Sales if order quantities are cut or stopped.
Systems	Business Objects (pulls information from AS400) Excel Access database in the near future

Organizational Chart

Distribution Operations (partial organization structure, part relevant to discussion of Lifestyle Drug Program only)

**Business Process Flow****1. REPORTS****1.1 Daily Dosage Summary Report**

The Daily Dosage Summary report is a Business Objects report run and distributed to DCMs on a weekly basis. This report summarizes sales/order information about “Lifestyle Drugs” identified by the DEA. There are currently four generic ingredients being focused on by the DEA:

- Oxycodone (example of a tracked drug is Percocet)
- Hydrocodone (example of a tracked drug is Vicoden)
- Alprazolam (example of a tracked drug is Xanax, an antidepressant)
- Phentermine (an appetite suppressant)

Any additions or deletions to the list of “Lifestyle Drugs” will be managed by the Regulatory Department. McKesson will monitor the “Lifestyle Drugs” focused on by the DEA. The list of substances monitored by McKesson will be adjusted when and if the DEA focus list is modified.

The Daily Dosage Summary report captures sales of products containing these generic ingredients which can be identified by a base code number. However, the base code number is not stored in McKesson’s sales history. Products containing the base codes are identified using a matrix of data from First Databank. The matrix includes a field that identifies the base code of ingredients included in each product. Products containing any of the base code numbers being focused on by the DEA can be identified using this matrix. A list of over 200 products containing the generic ingredients was identified by the Business Intelligence group and validated by the Regulatory Department. Any of those products with sales over a specified threshold are included in the Daily Dosage Summary report. The sales quantity is measured by dose rather than ordering unit and the current volume threshold is 8,000 doses. The threshold was determined by the Regulatory Department.

Because the list of products being monitored was determined by Business Intelligence, it is possible not all of the products containing one of the generic ingredients were included. It is possible that the controlled substances being monitored are being underreported. In the future the matrix from First Database will be linked to the list of generic ingredients focused on by the DEA and selection will be automated. Automating the selection process will decrease the risk products containing the Lifestyle Drugs are missed in the Daily Dosage Summary report.

This report was implemented in May 2007. Each DC receives a report and must review all customers that appear on the weekly reports. The report is cumulative through the month. Then the count starts over at the beginning of each month.

Although McKesson typically directs customers to order from only one DC, it is possible for a customer to order products from multiple DCs. Since the Daily Dosage Summary report is organized by DC, a customer may be on multiple DC reports. In that case the Data Analyst coordinates with the two DCMs to determine which will handle the customer review. On the other hand, situations where a customer is using more than one DC and the sales of "Lifestyle Drugs" at either DC is not greater than 8,000 doses but the total sales is greater than 8,000 doses would be missed by the current process. Additionally, customers with multiple accounts at a single DC with aggregate sales exceeding the thresholds are being missed by the current process.

The DCs are burdened by the amount of information on one report. Meaning, a customer that has already been reviewed and the sales quantity determined to be legitimate will continue to be included on the report as long as the volume is above the threshold. Also, it is not possible to tell from the report what stage of review the customer is in. If the DCs become overwhelmed by the LDMP, something will be missed.

1.2 Dosage Limit Tracing Detail

The Dosage Limit Tracing Detail report is a Business Object report that can be run on-demand. The report is used by the DC to research customers appearing on the Daily Dosage Summary report. It gives more detail of the customer's sales history.

2. DCM REVIEW

The DC must complete a review for every customer that appears on the Daily Dosage Summary report. The review process includes three tiers.

2.1. LEVEL I

The first level review requires the DCM to evaluate the customer's purchase history for the prior three months. The first time the customer appears on the report the DCM must also compile a customer profile. The DCM does not have to prepare the customer profile for chain and national customers; the profile would have already been prepared.

If the sales are deemed to be reasonable and no further investigation is needed, the LDMP (Lifestyle Drug Monitoring Program) Review Sign Off is completed. If the first level review is inconclusive, a level two review is performed and order quantities are cut.

2.2. LEVEL II

The second level review requires the DCM to conduct a customer site examination and possibly an interview with the customer. More than one person should be involved with a site visit. A "Declaration of Controlled Substances Purchases" is obtained from the customer at the time of the interview. Again, if the sales are deemed to be reasonable and no further investigation is needed, the LDMP Review Sign Off is completed. If the second level review is inconclusive, a level three review is performed.

2.3. LEVEL III

The third level review requires the DCM to escalate the matter to Regulatory Affairs and the Regional SVP. At this level of review the local DEA office or DEA Headquarters may also be

contacted. The Law Department and Senior Management will be consulted. The final decision regarding the legitimacy of the sales or action to be taken will be determined by the Law Department and the SVP. The LDMP Review Sign Off is also completed if sales are determined to be legitimate.

At any stage in the review process, Regulatory Affairs will notify the DEA headquarters and local office regarding any findings and any decision regarding continued business with the customer. Additionally at each step of the review process, the conclusion/findings are documented in the LDMP Tracking Spreadsheet. Each DC maintains this log of review results and submits it to the Data Analyst at month end.

3. MONTH-END PROCESS

Regulatory Affairs will maintain copies of the month-end Daily Dosage Summary Report. The DCs submit their month-end LDMP Tracking Spreadsheet to Regulatory Affairs. Deadline to submit the log is the 10th of the month. If the customer had been on the report in the previous month and the change is not over 25%, the DC does not have to resubmit. The review process would start over at the beginning of each quarter.

The Data Analyst consolidates the individual LDMP Tracking Spreadsheet for each individual DC into one master spreadsheet. Missing information is identified. And, some basic analysis is done on the consolidated information. The comments are reviewed and Lifestyle Drug sales at more than one DC are identified. A rolling six month sales history is maintained in the LDMP Tracking Spreadsheet, so this must be updated at month-end. Regulatory Affairs also receives electronic copies of the documents related to all investigations. All documentation will be maintained for at least two years.

There currently is not a secondary review of the consolidated LDMP Tracking Spreadsheet. The DCs have ultimate responsibility for the review.

4. FUTURE STATE

The Lakeland DC developed an Access database to aid in researching customers on the Daily Dosage Summary report. The System Developer and the Data Analyst are currently working with the Inventory Manager at Lakeland to further develop this Access database to replace the current process. Not only will the Access database house the information that is currently provided through the Daily Dosage Summary report, but the Access database will also store the review documentation in a central location. Consistent documentation would be ensured by using reminder flags in the database. Users will be limited to password protected forms. Certain fields will have to be completed before the user could move on. The tables and the database itself will also be password protected. A standard change control process will be in place; the databases will be backed up weekly.

Each DC will have an instance of the Access database. At month-end, review information from the individual databases will be pushed to a central database. This new database solution should be implemented in two months (by October 2007).

A process for evaluating the dosage threshold is also being considered. The Access database will allow dosage thresholds to be identified for each product monitored at each DC. For example if a customer is flagged for review and after investigation it is determined that the sales quantity is appropriate for that customer, the threshold for that customer could be modified to reflect a more accurate level. Changes to the threshold will be reported to the Data Analyst. A mechanism to automatically adjust the threshold downward if sales decrease over time would also be incorporated.

There may also be other ways sales should be looked at. For example, a quantity threshold may not be the only appropriate way to monitor sales. For example the Anchorage DC sales of the "Lifestyle Drugs" were below the 8,000 dosage threshold. However, when six months of sales data was reviewed, the current month sales were a 110% greater than the six month trend. Should percentage increase and decrease also be considered?

To address the issue of a customer using more than one DC or having more than one account, going forward all sales will be accumulated by the DEA number and home DC. There is a Business Objects request currently underway for this.

5. AREAS TO LOOK AT

Process for documenting/reviewing who goes out to customer site

How are the DCs retaining paper documentation of their reviews (record retention what, where, how long, etc). Only electronic copies of review documentation are being sent to the Data Analyst.

Are the DCs regularly sending review documentation to the Data Analyst; is all the required review documentation being sent to the Data Analyst

Examples of good review processes: Denver, Lakeland

Examples of review processes not as good: Birmingham, former DNK facilities, facilities that have lower skills in Business Objects, Access, and Excel find it harder (like Honolulu and Birmingham).